

REMARKS

Claims 1, 3, 5, and 22-24 are pending. Claims 1, 3, 5, and 22 stand rejected under 35 U.S.C. § 112, first paragraph. Applicants address this rejection as follows.

Claim amendments.

Claim 1 has been amended to incorporate the features of claim 22. In view of this amendment, claim 22 has been canceled. In addition, claim 23 has been rewritten in independent form. No new matter has been added by these amendments. For the record, Applicants note that the present amendments were made solely to expedite prosecution and Applicants reserve the right to pursue the canceled subject matter in this or a continuing application.

Rejection under 35 U.S.C. § 112, first paragraph.

Claims 1, 3, 5, and 22 stand rejected under 35 U.S.C. § 112, first paragraph, for an asserted lack of a written description of the invention in Applicants' specification. In particular, the Office asserts (page 5):

[T]he specification fails to adequately describe other nucleic acid sequences that encode a serotonin-gated anion channel, or even more generally what would be considered or defined as a "MOD-1" serotonin-gated anion channel that differentiates it from another serotonin-gated anion channel which is not MOD-1. Even a sequence that hybridize[s] to the specific disclosed sequences fails to adequately set forth with any specificity the essential elements of the polynucleotide that distinguish it as a serotonin-gated channel or a MOD-1.

Applicants respectfully disagree.

To fulfill the written description requirement of § 112, the patent specification does not need to describe exactly all the subject matter that is claimed. *In re Daniels*, 114 F.3d 1452, 46 U.S.P.Q.2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 117 (Fed. Cir. 1985). Rather, the specification must clearly allow a person of ordinary skill in the art to recognize that the inventor has invented what is claimed. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor “was in possession of the invention” at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

Further, under *Regents of University of California v. Eli Lilly & Co.*, 119 F.3d 1159, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), “every species in a genus need not be described in order that a genus meets the written description requirement.” 43 U.S.P.Q.2d at 1405 (citing *Utter v. Hiraga*, 845 F.2d 993, 6 U.S.P.Q.2d 1709 (Fed. Cir. 1988) (“A specification may, within the meaning of § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.”) Applicants have met these standards.

Applicants’ specification would certainly indicate to one of ordinary skill in the art that Applicants discovered a family of functional serotonin-gated anion channels. The

specification clearly describes to the skilled worker what is claimed. Claim 1, as amended, is directed to a substantially pure nucleic acid sequence encoding a serotonin-gated anion channel and requires the anion channel to be regulated by serotonin binding and to selectively permit passage of anions from one side of said channel to the other. In addition, claim 1 requires the nucleic acid sequence to hybridizes to the complement of the sequence of SEQ ID NO:2 under specific hybridization conditions.

The specification, for example, at page 24, line 8, to page 25, line 3, teaches that MOD-1 forms a serotonin-gated anion channel. In particular, Applicants submit that, even though the claimed invention is exemplified by a single serotonin-gated anion channel, one of skill in the art reading this specification would have readily recognized that this gene was provided for the purpose of illustrating the invention and that Applicants' invention included any functional serotonin-gated anion channel that is structurally related, as defined by the ability of nucleic acid sequence encoding this channel to hybridize under stringent conditions to the nucleic acid sequence of SEQ ID NO:2. For instance, at page 16, lines 8-10, the specification states that, "preferably the nucleic acid sequence encoding a serotonin-gated anion channel hybridizes to a *mod-1* nucleic acid sequence" (emphasis added). Such hybridization techniques are described quite specifically, for example, at page 35, lines 11-20 (and now in claim 1). In view of these teachings, the specification clearly conveys Applicants' presently claimed invention to those persons of skill in the art. The description in the specification also allows the

skilled worker to identify and recognize other species falling within the present claims. Based on this description, one skilled in the art would recognize that Applicants' invention encompassed, not one gene, but a family of genes encoding serotonin-gated anion channel polypeptides, and, on this basis alone, the written description rejection may be withdrawn.

Moreover, Applicants submit that their specification provides a written description of the presently claimed invention in sufficient detail to satisfy the standard set by the Federal Circuit in *Lilly*. In particular, this case specifically states that the written description of a genus of DNA may be achieved by a "recitation of structural features common to members of the genus." *Lilly*, 43 U.S.P.Q.2d 1398, 1406.

Applicants point out that the description of the claimed invention in Applicants' specification does not rely simply on the disclosed nucleic acid sequence encoding the serotonin-gated anion channel. Rather, the present specification describes a class of nucleic acid sequences that specifically hybridize to the sequence of SEQ ID NO:2 under specific conditions and that encode polypeptides that function as serotonin-gated anion channels. The specification thereby describes the serotonin-gated anion channels by specific structural features that are common to the class, as well as by functional features.

Applicants' specification therefore provides a description of the class of nucleic acid molecules encompassed by the present claims in a form entirely consistent with the

standard set out in *Lilly*, and, on this basis, the 35 U.S.C § 112, first paragraph, rejection should be withdrawn.

Applicants' specification also satisfies the written description requirement as set forth in the U.S. Patent & Trademark Office's Written Description Guidelines (<http://www.uspto.gov/web/menu/written.pdf>; "the Guidelines"). In particular, the Guidelines provide an example (Example 9:Hybridization), where a single cDNA species which encodes a protein that binds to a dopamine receptor and stimulates adenylate cyclase is disclosed in the specification. The claim, in Example 9 of the Guidelines, is directed to a genus of nucleic acids all of which must hybridize under highly stringent conditions with the disclosed cDNA and must encode a protein with a specific activity. In concluding that the written description requirement was satisfied in this Example, the Guidelines state:

[A] person of skill in the art would not expect substantial variation among species encompassed within the scope of the claims because the highly stringent hybridization conditions set forth in the claim yield structurally similar DNAs. Thus, a representative number of species is disclosed, since highly stringent hybridization conditions in combination with the coding function of DNA and the level of skill and knowledge in the art are adequate to determine that applicant was in possession of the claimed invention. (emphasis added)

The facts of the present case are squarely within these Guidelines. Applicants' claim 1 encompasses a nucleic acid molecule that specifically hybridizes to the complement of the sequence set forth in SEQ ID NO:2 under conditions that one skilled

in the art would recognize to be stringent. (These conditions are described as high stringency conditions at page 35, lines 11-15, of the specification.) Claim 1 also requires the nucleic acid molecule to encode an anion channel that is regulated by serotonin binding and to selectively permit passage of anions from one side of the channel to the other. As in Example 9, Applicants' specification describes (i) at least a single species of a nucleic acid molecule falling within the scope of the claimed genus and (ii) an activity of the protein encoded by the nucleic acid molecule (i.e., serotonin-gated anion channel function). A person of ordinary skill in the art would not expect substantial variation among species encompassed with the scope of the invention as claimed. The stringent hybridization requirement necessarily yields structurally similar nucleic acids which, when combined with the functionality requirement, describes a genus of nucleic acid molecules. Therefore, in this case, as in Example 9, the single disclosed species is representative of the genus. Applicants submit that the written description rejection should be withdrawn.

CONCLUSION

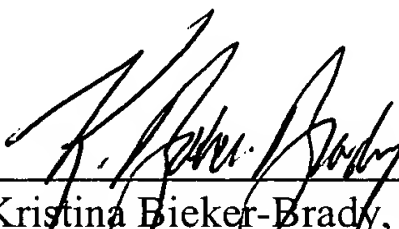
Applicants submit that the application is now in condition for allowance and this action is hereby respectfully requested.

Enclosed are a Petition to extend the period for replying to the Office Action for three (3) months, to and including December 16, 2004, and a check in payment of the required extension fee.

If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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